CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 40334

MICROBIOLOGY REVIEW

OFFICE OF GENERIC DRUGS

HFD-620

Microbiology Review #1 February 3, 2000

A. 1. **ANDA** 40-334

APPLICANT: Gensia Laboratories, Ltd.

17 Hughes

Irvine, CA 92618

2. PRODUCT NAME: Fluorouracil Injection, USP

- 3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: 50 mg/mL (50mL & 100mL/vial), for intravenous injection
- 4. METHOD(S) OF STERILIZATION:
- 5. PHARMACOLOGICAL CATEGORY: antineoplastic
- B. 1. DATE OF INITIAL SUBMISSION: August 31,1998

 Subject of this Review (Received September 1, 1998)
 - 2. ASSIGNED FOR REVIEW: February 2, 2000
 - RELATED DOCUMENTS:

 DMF /
 DMF
- C. REMARKS: The application is recommended for approval by all other review disciplines. The application is pending approval upon an acceptable sterility assurance review.

 NOTE TO CHEMIST: The review Chemist has noted, as a deficiency, that the applicant should include annual

deficiency, that the applicant should include annual sterility and endotoxin testing, in addition to testing at T=0 and expiry, as a part of their stability protocol. Annual sterility and endotoxin testing are not considered requirements by the review microbiologist.

D. <u>CONCLUSIONS</u>: The submission is **not recommended** for approval on the basis of sterility assurance. Specific comments regarding the process are provided

in "E. Review Notes" and a Microbiologist's draft of deficiencies to be provided to the Applicant found at the end of the review.

Lynne A Ensor, Ph. D.

Redacted /3

pages of trade

secret and/or

confidential

commercial

information

Micro #/

OFFICE OF GENERIC DRUGS

HFD-620

Microbiology Review #2 February 10, 2000

A. 1. **ANDA** 40-334

APPLICANT: Gensia Laboratories, Ltd.

17 Hughes

Irvine, CA 92618

2. PRODUCT NAME: Fluorouracil Injection, USP

- 3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: 50 mg/mL (50mL & 100mL/vial), for intravenous injection
- 4. METHOD(S) OF STERILIZATION:
- 5. PHARMACOLOGICAL CATEGORY: antineoplastic
- B. 1. DATE OF INITIAL SUBMISSION: August 31,1998
 - 2. DATE OF AMENDMENT: February 4, 2000

 Subject of this Review (Received February 7, 2000)
 - 3. ASSIGNED FOR REVIEW: February 10, 2000
 - 4. RELATED DOCUMENTS: N/A
- C. <u>REMARKS</u>: The subject amendment provides responses to the microbiology deficiencies provided to the applicant in the February 4, 2000 facsimile.
- D. <u>CONCLUSIONS</u>: The submission **is recommended** for approval on the basis of sterility assurance. Specific comments regarding the aseptic filling process are provided in "E. Review Notes".

Lynne A Ensor, Ph. D.

cc: Original ANDA 40-334

Duplicate ANDA Division Copy Field Copy

Drafted by L. Ensor, HFD 600 v:microrev\40334a Initialed by M. Fanning 11600

Redacted 2

pages of trade

secret and/or

confidential

commercial

information

micro Review #2